

Question Q217

National Group: Canada

Title: The patentability criterion of inventive step /

non-obviousness

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Questions

I. ANALYSIS OF CURRENT LAW AND CASE LAW

The Groups are invited to answer the following questions under their national laws:

Level of Inventive Step / Non-Obviousness

1. What is the standard for inventive step / non-obviousness in your jurisdiction? How is it defined?

Section 28.3 of the current Canadian *Patent Act* sets out that an invention must be non-obvious:

The subject-matter defined by a claim in an application for a patent in Canada must be subject matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to:

(a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge,

directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and

(b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

Recently, the Supreme Court of Canada in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, [2008] 3 S.C.R. 265, 2008 SCC 61 (hereinafter "Sanofi") at para. 67 set out the following four step test (hereinafter the "Sanofi test") for assessing obviousness, based on the United Kingdom decisions *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*, [1985] R.P.C. 59 (C.A.) (hereinafter "Windsurfing") and Pozzoli SPA v. BDMO SA, [2007] F.S.R. 37 (p. 872), [2007] EWCA Civ 588 (hereinafter "Pozzoli"):

- (a) Identify the notional "person skilled in the art";
 - (b) Identify the relevant common general knowledge of that person;
- (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
- (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
- (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

The Court further held that an "obvious to try" test may be appropriate at step (4) of the obviousness inquiry, for example in "areas of endeavour where advances are often won by experimentation" (*Sanofi*, at para. 69).

It should be noted that the term "inventive concept" as recited in step (2) of the *Sanofi* test is imported from United Kingdom jurisprudence and is not referred to in the current Canadian *Patent Act*.

2. Has the standard changed in the last 20 years? Has the standard evolved with the technical / industrial evolution of your jurisdiction?

Non-obviousness was only included as an express provision in the Canadian *Patent Act* in 1996. However, obviousness has always been a bar to patentability in Canada.

The traditional and most often cited test for obviousness in Canada was articulated by Justice Hugessen in *Beloit Canada Ltd. v. Valmet Oy*, (1986), 8 C.P.R. (3d) 289 at 294 (F.C.A.) (hereinafter "*Beloit*"). Hugessen held an invention is obvious when a person skilled in the art could have come "directly and without difficulty" to the solution taught by the patent (emphasis added):

The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician

skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in the light of the state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy.

The 2008 decision of the Supreme Court of Canada in Sanofi is the most significant development with respect to obviousness in Canada in recent years. In affirming the use of the Windsurfing/Pozzoli questions in an obviousness inquiry, the Supreme Court cautioned that "the restrictiveness with which the Beloit test has been interpreted in Canada should be re-examined" and that the test was never intended to be "applied in an acontextual manner applicable to all classes of claims" (Sanofi, paras. 60 and 62, respectively).

In particular, the Court in *Sanofi* held at para. 68 that an "obvious to try test" may be of value when assessing inventions in the pharmaceutical field:

In areas of endeavour where advances are often won by experimentation, an "obvious to try" test might be appropriate. In such areas, there may be numerous interrelated variables with which to experiment. For example, some inventions in the pharmaceutical industry might warrant an "obvious to try" test since there may be many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances.

The applicability of the *Sanofi* "obvious to try" step to inventions outside of those in the pharmaceutical field has not been clarified to date.

3. Does your patent-granting authority publish examination guidelines on inventive step / non-obviousness? If yes, how useful and effective are the guidelines?

The Canadian Intellectual Property Office publishes the Manual of Patent Office Practice (MOPOP). The MOPOP is a guide for Patent Examiners and Applicants and does not have the force of law.

The MOPOP section on obviousness (§15.01.02) was last updated in March 1998 and paraphrases the *Beloit* test:

The test for obviousness is essentially whether or not an unimaginative skilled technician would, in the light of the state of the art and common general knowledge at the claim date, be led directly and without difficulty to the invention covered by the claim i.e. subject matter defined by the claim.

MOPOP notes that "[c]are must be exercised in assessing whether the differences between the claimed invention and the disclosure of the prior art, even if minor, produce unexpected results, in which event the element of unobviousness could be present". MOPOP also provides a number of examples of modifications which would be considered obvious, for example, substituting superior for inferior materials in the manufacture of parts for a machine, changing the size or

dimensions of an object and omitting one or more parts of a machine with a corresponding omission of function.

However, given the brevity of the obviousness guidelines in MOPOP and the fact that they have not been updated since the Supreme Court of Canada's holding on obviousness in *Sanofi*, the guidelines are of limited practical value. Patent Examiners and Applicants are more likely to rely on case law (e.g., *Sanofi*) when arguing obviousness.

4. Does the standard for inventive step / non-obviousness differ during examination versus during litigation or invalidity proceedings?

The same legal standard applies both during patent examination and during litigation or invalidity proceedings. However, the nature of litigation normally results in a significantly more rigorous analysis and application of the tests for non-obviousness during court proceedings as opposed to patent prosecution.

Construction of Claims and Interpretation of Prior Art

5. How are the claims construed in your jurisdiction? Are they read literally, or as would be understood by a person skilled in the art?

A patent is to be given a purposive construction in light of the background in the art and the understanding of a person skilled in the art as at the date of publication of the application and in light of specification as a whole. The language of the specification should be interpreted in its context having regard to the meaning of technical terms, the ordinary meaning of non-technical words and any particular definitions provided by the inventor. The patent is to be interpreted without reference to extrinsic evidence such as the record file of the application or other writings of the inventor. Expert evidence is admissible to instruct the Court as to the background in the art and the understanding of a person skilled in the art. (Such expert evidence is not considered to be extrinsic evidence.) These principles apply to the whole of the patent including the claims.

In interpreting the claims of the patent, the following principles are also applicable. The claims are to be construed in light of the whole specification, but plain language is not to be expanded or restricted by references in the disclosure. The whole of a claim is to be considered. There should be consistency of interpretation amongst the claims. The Court must construe the claims, not redraft them. Each claim is, if possible, to be given a distinct meaning. The claims language will, on a purposive construction, show that some elements of the claimed invention are essential while others are non-essential. As to the latter principle, in *Free World Trust v. Electro Santé Inc.* 2000 SCC 66 at para. 55, Binnie J. for the Supreme Court of Canada said:

It would be unfair to allow a patent monopoly to be breached with impunity by a copycat device that simply switched bells and whistles, to escape the literal claims of the patent. Thus the elements of the invention are identified as either essential elements (where substitution of another element or omission takes the device outside the monopoly), or non-essential elements (where substitution or omission is not necessarily fatal to an allegation of infringement). For an element to be considered non-essential and thus substitutable, it must be

shown either (i) that on a purposive construction of the words of the claim it was clearly not intended to be essential, or (ii) that at the date of publication of the patent, the skilled addressees would have appreciated that a particular element could be substituted without affecting the working of the invention, *i.e.*, had the skilled worker at that time been told of both the element specified in the claim and the variant and "asked whether the variant would obviously work in the same way", the answer would be yes ... In this context, I think "work in the same way" should be taken for our purposes as meaning that the variant (or component) would perform substantially the same function in substantially the same way to obtain substantially the same result.

6. Is it possible to read embodiments from the body of the specification into the claims?

The claims are to be construed in light of the whole specification. In *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504, 56 C.P.R. (2d) 145 (S.C.C.) (hereinafter "*Consolboard*"), Dickson J. said: "We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance." In short the claims are to be construed in context, but it is still the text of the claims that is to be interpreted. If the language of a claim is plain and unambiguous, the courts are not to restrict or qualify the scope of such claim by reading in a limitation from the disclosure, nor to expand the monopoly as expressed in the claim by reference to the body of the specification.

Typically, the embodiments are merely examples and are not intended to qualify the claims, but embodiments may in some cases assist in understanding the claims or particular claims.

7. How is the prior art interpreted? Is it read literally or interpreted as would be understood by a person skilled in the art? Is reliance on inherent disclosures (aspects of the prior art that are not explicitly mentioned but would be understood to be present by a person skilled in the art) permitted?

Prior art is to be interpreted in accordance with the same principles as are applicable to interpreting the patent. A prior art reference is to be read in light of the background in the art and the understanding of a person skilled in the art as at the date of publication of the application and in light of document as a whole.

In assessing obviousness, the prior art as so interpreted is assessed in light of the common general knowledge of the person skilled in the art at the claim date of the claim in issue (the priority date if applicable to that claim, otherwise the filing date). Common general knowledge means knowledge generally known by persons skilled in the relevant art at the relevant time. It includes what the person may reasonably be expected to know and to be able to find out. It is all the knowledge which is generally known and generally regarded as a good basis for further action by the bulk of those engaged in the field to which that invention relates. A person skilled in the art is expected to be reasonably diligent in keeping up with advances in the field to which the patent relates and their common knowledge undergoes continuous evolution and growth.

8. Do the answers to any of the questions above differ during examination versus during litigation?

The principles as to construction of the patent and as to interpretation of the prior art are applicable during examination as well as in litigation, but during examination it is not common to present expert evidence as to these issues.

Combination or Modification of Prior Art

9. Is it proper in your jurisdiction to find lack of inventive step or obviousness over a single prior art reference? If yes, and assuming the claim is novel over the prior art reference, what is required to provide the missing teaching(s)? Is argument sufficient? Is the level of the common general knowledge an issue to be considered?

The response to Question 1 above set out the four step *Sanofi* test for assessing obviousness, as endorsed the Supreme Court of Canada.

The state of the art in step (3) of *Sanofi* may be assessed from one or more prior art references (*Creations 2000 Inc. v. Canper Industrial Products Ltd.* (1999), 22 C.P.R. (3d) 178 (F.C.A.) at 182). Common general knowledge assessed in step (1) of the *Sanofi* test is used to supplement information contained in the state of the art. As discussed in the response to Question 7 above, common general knowledge means knowledge generally known by persons skilled in the relevant art at the relevant time (*Sanofi* at para. 37), and may or may not include prior art references that form the state of the art.

The "inventive concept" to be identified at step (2) of the *Sanofi* test does not refer to what is new about the claimed invention. Rather, "identifying the inventive concept of the claim in question" means understanding the claimed invention, without regard to the state of the art (*Pozzoli* at para. 21).

The differences identified at step (3) of the *Sanofi* test are the differences between the invention and the state of the art. According to step (4) of the *Sanofi* test, an invention is obvious when the notional person skilled in the art, armed with the relevant common general knowledge, can arrive at the claimed invention using the prior art references without any degree of inventiveness.

Obviousness is thus a finding of fact, based on evidence of who is the person skilled in the art, what constitutes common general knowledge and what prior art forms the state of the art. When these underlying facts are not in dispute, argument may be sufficient to establish obviousness.

10. What is required to combine two or more prior art references? Is an explicit teaching or motivation to combine required?

Two or more prior art references can be combined when it is shown that a person skilled in the art would have been led to combine the relevant elements from the mosaic of prior art without ingenuity or inventiveness (*Laboratoires Servier v. Apotex Inc.*, 2008 FC 825 at para. 254, hereinafter "*Laboratoires Servier FC*", aff'd 2009 FCA 222, hereinafter "*Laboratoires Servier FCA*"). The Supreme Court of Canada has, however, warned against using hindsight analysis when combining two or more prior art references (*Consolboard* at 533):

It is often fairly easy for a defendant in an infringement suit, in hindsight, to thoroughly search and selectively unearth pieces of prior art in various fields, interfelt them with common knowledge, then say it was all very plain: an ordinary skilled workman would easily and readily have been led to what the "inventor" of the patent in suit now asserts.

While Canadian courts have not held that an explicit teaching or motivation to combine is required, teaching or motivation to combine are relevant factors to consider in step (4) of the *Sanofi* test for assessing obviousness as set out in the response to Question 1 above. The Federal Court of Appeal has stated that motivation to combine may provide a reason why one might reasonably expect the notional person skilled in the art to combine prior art references to come up with the claimed invention (*Janssen-Ortho Inc. v. Novopharm Ltd.*, 2007 FCA 217 at para. 25, hereinafter "*Janssen-Ortho*"). Similarly, teaching to combine would lead the notional person skilled in the art to combine prior art references without ingenuity or inventiveness.

11. When two or more prior art references are combined, how relevant is the closeness of the technical field to what is being claimed? How relevant is the problem the inventor of the claim in question was trying to solve?

The closeness of the technical field is a relevant factor to consider in step (4) of the *Sanofi* test.

The Federal Court has held that it is not always improper to rely on prior art references outside the relevant technical field, but "it cannot be assumed that the unimaginative, non-inventive technician skilled in the art would consider art in other fields" (*Laboratoires Servier FC* at para. 236). The Federal Court has also stated: "[the plaintiff] contends it is permissible to [combine prior art references] if they are in the same technical field. I do not agree. In my judgment it is only permissible to read two documents together if it is obvious to do so" (*Eli Lilly & Co. v. Apotex Inc.*, 2009 FC 991 at para. 491, hereinafter "*Apotex*", quoting from *Scinopharm Taiwan Ltd. v. Eli Lilly & Co.*, [2009] EWHC 631 (Eng. Patents Ct.)). Whether or not the notional person skilled in the art would look to prior art references outside the relevant field of invention is a question of fact (*Laboratoires Servier FCA* at para. 73).

The problem which the inventor was trying to solve is a relevant factor to consider in steps (3) and (4) of the test for assessing obviousness.

The Federal Court has held that identification of the problem the inventor was trying to solve may constitute an inventive step (*Ductmate Industries Inc. v. Exanno Products Ltd.* (1984), 2 C.P.R. (3d) 289 at 306 (Fed. T.D.)). Thus, identification of the problem contributes to the difference between the invention and the state of the art, as determined in step three of the test for assessing obviousness.

The Federal Court of Appeal has held that a factor to consider when assessing obviousness is the "motivation in existence at the time the alleged invention to solve a recognized problem" (*Janssen-Ortho* at para. 25). The Court elaborated:

If within the relevant field there is a specific problem that every one in the field is trying to solve (a general motivation), it may be more likely that the solution, once found, required inventive ingenuity. On the

other hand, if there is a problem that only the claimed inventor is trying to solve (a unique or personal motivation), and no one else has a reason to address that problem, it may be more likely that the solution required inventive ingenuity.

12. Is it permitted in your jurisdiction to combine more than two references to show lack of inventive step or obviousness? Is the standard different from when only two references are combined?

In Canada, there is no rule—statutory or judge-made—prohibiting the combination of more than two prior art references in establishing obviousness. The "common general knowledge" and "state of the art", as contemplated by the Supreme Court of Canada in formulating the *Sanofi* test is broad enough to embrace a "mosaic" of prior art (*Apotex* at paras. 95-104). The standard for assessing obviousness does not change when combining more than two prior art references. Courts have, however, expressed scepticism towards a finding of obviousness when an attempt is made to combine a large number of references (*Consolboard* at 533).

13. Do the answers to any of the questions above differ during examination versus during litigation?

The law of obviousness applied by examiners during examination should be the same as that applied by the courts during litigation. CIPO's official position on the law of obviousness is set out at §15.01.02 of the MOPOP (cited in the response to Question 3).

Technical Problem

14. What role, if any, does the technical problem to be solved play in determining inventive step or non-obviousness?

The problem/solution approach for assessing non-obviousness, while possibly persuasive, is not determinative under Canadian law.

If it is to be used as a consideration for non-obviousness, it may as part of the "obvious to try" test at step (4) of the obviousness inquiry, for example in "areas of endeavour where advances are often won by experimentation" (*Sanofi* at para. 69).

The technical problem and the solution have very different meanings in Canada than in Europe.

In Canada, the inventive concept of a claim under examination is identified without regard to the prior art. Identifying the problem being addressed by the solution of the claim is done in the context provided by the description, and not by reference to the closest prior art.

Where the existence or nature of a problem was unobvious, identifying the problem can contribute to the necessary inventive step.

15. To what degree, if any, must the technical problem be disclosed or identified in the specification?

The technical problem need not be disclosed or identified in the specification.

It should be understandable by a person skilled in the art from the description, in accordance with paragraph 80(1)(d) of the Canadian *Patent Rules* (for applications filed on or after October 1, 1996).

- 80. (1) The description shall
- (a) state the title of the invention, which shall be short and precise and shall not include a trade-mark, coined word or personal name;
- (b) specify the technical field to which the invention relates;
- (c) describe the background art that, as far as is known to the applicant, can be regarded as important for the understanding, searching and examination of the invention;
- (d) describe the invention in terms that allow the understanding of the technical problem, even if not expressly stated as such, and its solution:
- (e) briefly describe the figures in the drawings, if any;
- (f) set forth at least one mode contemplated by the inventor for carrying out the invention in terms of examples, where appropriate, and with reference to the drawings, if any; and
- (g) contain a sequence listing where required by subsection 111(1).

It should be noted that the importance of paragraph 80(1)(d) is somewhat reduced by paragraph 80(2) of the Patent Rules (for applications filed on or after October 1, 1996).

80. (2) The description shall be presented in the manner and order specified in subsection (1) unless, because of the nature of the invention, a different manner or a different order would afford a better understanding or a more economical presentation.

It should be noted that there is no jurisprudence in Canada on the application of Rule 80(1)(d) and Rule 80(2) and on the relationship between sufficiency of description (as per Rule 80) and determination of obviousness.

It should be noted that if a problem is positively stated in the description, it could raise utility issues at trial. Indeed, stating a problem that the invention solves in the description could be argued to be equivalent to naming a use for the invention. Naming a use of the invention adds a burden for the Applicant to then describe an invention that works and achieves the use that is identified in the description. A validity attack could then be based on the argument that the invention does not fulfil this use.

Advantageous Effects

16. What role, if any, do advantageous effects play in determining inventive step or non-obviousness?

Advantageous effects may be relevant in determining non-obviousness (Canadian courts have not historically relied upon "inventive step"). In particular, advantageous effects have been considered in identifying the inventive concept (step (2) of the *Sanofi* test) and in determining whether the difference between the inventive concept and the state of the art is obvious (steps (3) and (4) of the *Sanofi* test).

Step (2) of the *Sanofi* test requires that the court identify the inventive concept of the claim or if that cannot be readily done, construe it. In circumstances where the inventive concept of the claims is not readily discernable from the claims, it is acceptable to read the specification to determine the inventive concept. In *Sanofi*, a selection patent case, the Court found that the inventive concept of the claims was "a compound useful in inhibiting platelet aggregation which has greater therapeutic effect and less toxicity" than other compounds.

Examples in the jurisprudence where advantages have been considered in assessing inventive concept include:

- "recognition of an advantage" (*Bridgeview Manufacturing Inc. v. 931409 Alberta Ltd.*, 2010 FCA 188 at para. 43);
- discovery of a new drug "coupled with its advantages" (Eli Lilly Canada Inc. v. Novopharm Ltd., 2010 FCA 197 at para. 57 and 64, hereinafter "Eli Lilly");
- discovery of a new use for an old compound (*Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536); and
- recognition that a compound selected from a previously disclosed genus exhibits "special property of an unexpected character", *i.e.*, a special advantage (*Sanofi* at para. 9).

As noted, advantageous effects are also relevant under steps (3) and (4) of the *Sanofi* test. For example, advantageous effects not disclosed in the prior art may be relevant in assessing the difference between the state of the art and the claimed invention. Advantages that are not predictable or readily identified may support a finding of non-obviousness.

17. Must the advantageous effects be disclosed in the as-filed specification?

The jurisprudence suggests that advantages must be disclosed in the as-filed specification in certain circumstances:

- When claiming a selection, "the advantage or the nature of the characteristic possessed by the selection must be stated in the specification in clear terms" (*Eli Lilly* at para. 78; *Sanofi* at para. 114).
- When a patent claims a new use for an old compound, the new use must be disclosed in the as-filed specification (*Apotex Inc. v. Hoffmann-La Roche Ltd.* (1989), 24 C.P.R. (3d) 289 (F.C.A.) at 298).

Whether advantageous effects must be disclosed in the as-filed specification for other subject matter has not been settled under Canadian law. While an applicant may attempt to rely upon undisclosed advantageous effects in order to overcome cited art during prosecution, such an approach may not survive judicial scrutiny during litigation. (Moreover, if an advantageous effect forms part of the utility of an invention, disclosure requirements under the law of utility will be engaged. The open question is whether a patentee may rely on advantageous effect.)

The Federal Court of Appeal has indicated that, when considering obviousness, advantages perceived only after the date of invention should not be given any weight: "[it is] difficult to envisage a situation where a subsequently recognized

advantage to a claimed invention would be of any assistance in determining whether inventive ingenuity was required to make it." (*Janssen-Ortho Inc.* at para. 26).

18. Is it possible to have later-submitted data considered by the Examiner?

Applicants can submit affidavits regarding advantageous effects to CIPO in response to an Examiner's obviousness rejection.

As discussed in the response to Question 17 above, the Courts have expressed scepticism about relying on advantages recognized after the invention date. As a result, the data supporting the advantage should probably have been available by the invention or claim date.

(This may create a problem where inventors are unaware of cited art prior to filing. For example, a pharmaceutical compound may be structurally similar to a prior art compound and have significantly better properties relative to the cited compound but comparative testing may not have been conducted.)

Moreover, as noted, utility requirements may be engaged if the advantage is an aspect of the utility. Under Canadian law utility must be demonstrated or based on a sound prediction by the Canadian filing date. After the fact validation of utility is not permissible (*Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77).

19. How "real" must the advantageous effects be? Are paper or hypothetical examples sufficient?

As noted in response to Question 17 above, Canadian courts have suggested that advantages must be disclosed in the context of selection and new use patents. Canadian law has not otherwise addressed whether advantages relied upon for non-obviousness must be disclosed in the specification. (A patentee, however, still must comply with separate disclosure requirements for utility. Hence, while relying on an undisclosed advantage may assist in rebutting an obviousness attack, this may raise other validity issues).

As to how "real" advantageous effects must be, recent jurisprudence suggests that, in assessing non-obviousness, the Courts will not question the existence of the advantageous effects. In *Eli Lilly*, the Federal Court of Appeal assessed obviousness without regard to whether the asserted advantages actually existed, apparently leaving that aspect of the analysis for consideration as an aspect of utility. (The *Eli Lilly* decision also involved a selection patent and as result the advantageous effects were apparently disclosed in the specification).

It is unclear under Canadian law whether the significance of an advantageous effect is a factor in analyzing obviousness or whether such an analysis is more properly a facet of utility.

Hypothetical or paper examples may be sufficient in the context of an obviousness analysis, although the existence (or non-existence) of the advantage may be considered as part of utility.

20. Do the answers to any of the questions above differ during examination versus during litigation?

The law of obviousness applied by examiners during examination is the same as that applied by the Courts during litigation. CIPO's official position on the law of obviousness is set out at §15.01.02 of the MOPOP (cited in the response to Question 3). Office practice, however, may be open to review by the Courts either in the context of an appeal from the refusal to grant a patent, or in a subsequent action on the validity of the patent. For example, the office practice of receiving later-submitted data may not survive a judicial challenge.

Teaching Away

21. Does your jurisdiction recognize teaching away as a factor in favor of inventive step/non-obviousness? Must the teaching be explicit?

"Teaching away" is not codified into any Canadian statute and is not explicitly mentioned in the MOPOP. Nonetheless, teaching away is an important consideration in establishing the state of the art and motivations of a skilled person during an obviousness inquiry, both during prosecution and before Canadian courts (*Beloit* at 296; *CertainTeed Corp. v. Canada (Attorney General)*, 2006 FC 436; *Illinois Tool Works Inc. v. Cobra Fixations* (2002), 20 C.P.R. (4th) 402 (Fed. T.D.) at para. 109; *Almecon Industries Ltd. v. Nutron Manufacturing Ltd.* (1996), 65 C.P.R. (3d) 417 (Fed. T.D.) at 440; *Janssen-Ortho* at para. 25).

The teaching need not be explicit. For example, in the chemical and pharmaceutical arts, the Court has considered statements in the prior art regarding the properties of *similar* compounds (*Janssen-Ortho Inc. v. Apotex Inc.*, 2009 FCA 212) and *general* types of chemical substituents (*Bayer AG v. Apotex Inc.*, 2003 FC 1199 at paras. 78-83) (*e.g.*, "smaller radicals always proved to be the best", and "bulkier [groups]... had deleterious results"), where the invention makes use of a specific compound and demonstrates surprising effects. Teaching away from "conventional wisdom" has also been considered by the Courts (*Beloit* at 296) in determining non-obviousness.

22. Among the other factors supporting inventive step / non-obviousness, how important is teaching away?

During examination, 'teaching away' can be crucial to rebutting an examiner's allegation that prior art features can be properly mosaiced together. Before the courts, 'teaching away' is one of several primary factors used to establish the relevant knowledge of a skilled person, and whether the invention was unexpected.

23. Is there any difference in how teaching away is applied during examination versus in litigation?

Under the *Sanofi* test, "teaching away" falls into the wider assessment of (i) the general state of the art (which includes attitudes, trends, prejudices, and expectations (see *Janssen-Ortho* at para. 25), and (ii) whether the differences between the inventive concept and the prior art would be obvious to such a person. In Canada, a claim may also be obvious if it is "obvious-to-try", though this is a more stringent test than the "worth a try" test of other jurisdictions (*Apotex v. Pfizer*, 2009 FCA 8; hereinafter "*Pfizer*"). In an assessment of "obvious-to-try", teaching away

may be relevant to determining whether there is a motivation in the prior art to find a solution to the problem which the patent addresses.

During examination, obviousness objections are not often set out using the *Sanofi* test unless an Examiner perceives that an impasse is imminent. At least initially, greater emphasis is placed on simply mosaicing features from different references. Generally, there is more flexibility in terms of how counter-arguments may be presented, and the crux of an argument could very well rest on an applied reference teaching away. However, a recent Federal Court decision indicates that Applicants should be wary of mischaracterizing the prior art as a whole with general statements to this effect (*Lundbeck Canada Inc. v. Ratiopharm Inc.*, 2009 FC 1102).

Secondary Considerations

24. Are secondary considerations recognized in your jurisdiction?

Yes. Canadian courts have recognized a number of secondary factors as relevant to an obviousness analysis.

25. If yes, what are the accepted secondary considerations? How and to what degree must they be proven? Is a close connection between the claimed invention and the secondary considerations required?

There is no accepted closed-list of secondary considerations. The following is a non-exhaustive list of factors that have been considered relevant to the obviousness inquiry by Canadian courts:

- (a) <u>Commercial success</u> Commercial success of an invention may be evidence of non-obviousness. See, *e.g., The King v. Uhlemann*, [1952] 1 S.C.R. 143 at 152.
- (b) Motivation at the time of invention to solve a recognized problem A long-felt need in the industry for the solution to a problem that was only solved once the invention was made is evidence that the invention is non-obvious. The failure of others to solve a known problem that was being actively pursued by others is a factor in an obviousness inquiry. In some cases, if the inventor is the only person motivated to solve a problem that may also be evidence that the solution is inventive, unless the solution required only commonplace thought and techniques. See, e.g., Janssen-Ortho at para. 25.
- (c) <u>History of the inventive process</u> The time and effort required to create an invention may be evidence that the invention was non-obvious. However, a patent may be non-obvious even if the invention was discovered quickly or by accident. See, *e.g.*, *GlaxoSmithKline Inc. v. Genpharm Inc.*, 2003 FC 1248 at para. 86.
- (d) Reaction to the invention Acceptance by the community to which the invention relates may be evidence of non-obviousness. A meritorious award granted for the invention may also be considered. Amazement following its public disclosure and imitation of the invention by others after its introduction are also factors suggesting non-obviousness. Another possible factor is that the invention has been widely used in preference to alternative devices in the

marketplace. See, e.g., Eli Lilly Canada Inc. v. Apotex Inc., 2007 FC 455 at para. 353.

(e) Attacking party itself sought to patent the invention – Where the party attacking a patent in a court proceeding itself sought to patent a similar invention, that fact may be strong evidence of the non-obviousness of the invention. See, e.g., Lubrizol Corp. v. Imperial Oil Ltd. (1990), 33 C.P.R. (3d) 1 (Fed.T.D.).

No factor alone is determinative. The application of these factors is dependent on the specific facts. In some cases, certain factors may be highly relevant, while in other cases, those same factors may be given little or no weight. The Federal Court of Appeal in *Janssen-Ortho* stated at para. 25: "[t]here is no single factual question or a set of questions that will determine every case, or any particular case."

The factual situation evidencing the factors is established on a normal evidentiary balance of probabilities. Establishing that the factual situation exists does not necessarily mean the factor is relevant to the determination of obviousness, since it there must also be some evidence that the facts (such as commercial success or meritorious awards) are due to the inventive ingenuity embodied in the product and not due to other aspects of the product. That is, there must be a close connection between the claimed invention and the secondary factors considered. For each factor, the essential question is whether the facts are evidence of the inventive ingenuity of the invention or something else. In particular, commercial success must be shown to derive from the inventive features. In *Janssen-Ortho*, the Federal Court of Appeal warned at para. 25 that commercial success "may also reflect things other than inventive ingenuity such as marketing skills, market power and features other than the invention".

26. Do the answers to any of the questions above differ during examination versus during litigation?

The same test applies both during patent examination and during litigation or invalidity proceedings. However, as mentioned above in response to Question 4, the nature of litigation normally results in a significantly more rigorous analysis of non-obviousness during court proceedings as opposed to patent prosecution. As such, the issue of secondary considerations is generally addressed in the context of litigation and not during the examination stage.

Other Considerations

27. In addition to the subjects discussed in questions 4 - 26 above, are there other issues, tests, or factors that are taken into consideration in determining inventive step / non-obviousness in your jurisdiction?

If yes, please describe these issues, tests, or factors.

Nothing further to be added.

Test

28. What is the specific statement of the test for inventive step/non-obviousness in your jurisdiction? Is there jurisprudence or other authoritative literature interpreting the meaning of such test and, if so, provide a brief summary of such interpretation.

The response to Question 1 above set out the four step *Sanofi* test for assessing obviousness as endorsed by the Supreme Court of Canada.

As discussed in the response to Question 1, step (4) of the *Sanofi* test may include a further "obvious to try" test. If an "obvious to try" test is warranted, the following non-exhaustive list of factors should be taken into consideration:

- (1) Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
- (2) What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
- (3) Is there a motive provided in the prior art to find the solution the patent addresses?

Since its decision date, the *Sanofi* test has been consistently followed by the Federal Court and Federal Court of Appeal in Canada, establishing it as the key test for obviousness in Canada.

In *Pfizer*, the Federal Court of Appeal further refined the "obvious to try" test set out in *Sanofi* by rejecting the "worth a try" test and instead focusing on the word "obvious" as meaning "very plain" or "more or less self-evident" (paras. 28-29):

I take it from this that the test adopted by the Supreme Court is not the test loosely referred to as "worth a try". After having noted Apotex' argument that the "worth a try" test should be accepted (para. 55), Rothstein J. never again uses the expression "worth a try" and the error which he identifies in the matter before him is the failure to apply the "obvious to try" test (para. 82).

The test recognized is "obvious to try" where the word "obvious" means "very plain". According to this test, an invention is not made obvious because the prior art would have alerted the person skilled in the art to the possibility that something might be worth trying. The invention must be more or less self-evident [...]

29. Does such test differ during examination versus during litigation?

The same test applies both during patent examination and during litigation or invalidity proceedings. However, as mentioned above, the nature of litigation normally results in a significantly more rigorous analysis of non-obviousness during court proceedings as opposed to patent prosecution.

Patent Granting Authorities Versus Courts

30. If there are areas not already described above where the approach to inventive step / non-obviousness taken during examination diverges from that taken by courts, please describe these areas.

Following the Supreme Court of Canada judgement in *Sanofi*, CIPO, on <u>May 14</u>, <u>2009</u>, released a "Practice Notice on Obviousness" (hereinafter "the practice notice") explaining how the judgement would be applied by CIPO during patent application examination.

In the practice notice, CIPO reviewed the four step approach promulgated in *Sanofi* and explained in its own words how it should be applied to the obviousness inquiry by providing guidelines on how to perform the identifications required by the test. However, stakeholder organizations such as the Intellectual Property Institute of Canada (IPIC) and the Fédération Internationale des Conseils en Propriété Industrielle (FICPI) pointed out that the practice notice was not wholly consistent with the ordered approach that has been set out in *Sanofi*.

Their comments may be found online:

- IPIC: http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapi/200709CommentaireIPIC-200709CommentIPIC-eng.pdf
- FICPI: http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/200709CommentaireFICPI-200709CommentFICPI-eng.pdf

On <u>November 2, 2009</u>, a revised practice notice was published by CIPO, addressing some, but not all the concerns raised by the above comments from IPIC and FICPI.

The remaining criticisms concerning the practice notice may be quickly summarized as follows:

- (1) The practice notice provides an incomplete list of obvious to try factors, The practice notice takes into consideration the first 3 factors, but excludes the "course of conduct" (or "history of the invention") inquiry;
- (2) The term "obvious to try" is equated with "obviousness", while it is only one factor to assist in the obviousness inquiry;
- (3) The practice notice states that the person of skill in the art will be identified "where necessary". As stated in *Sanofi*, identification of the person of skill in the art is <u>not</u> an optional step;
- (4) The practice notice explains that Examiners may refer to information that they believe is common general knowledge, and that *they need not identify* documents establishing the common general knowledge;
- (5) The practice notice frames the identification of the inventive concept in the context of the requirement for unity of invention (section 36 of the patent rules). No basis whatsoever exists in *Sanofi* linking the

identification of the inventive concept to the Canadian concept of unity of invention:

The practice notice makes reference to a "problem/solution" approach. Kindly refer to our answer to Questions 14 and 15 in this regard.

31. Is divergence in approach to inventive step / non-obviousness between the courts and the patent granting authority in your jurisdiction problematic?

The relatively new nature of the practice notice regarding obviousness makes it such that the divergences identified in the approach to obviousness promulgated by CIPO and that of the court has had, for the time being, relatively little impact on the day to day practice of patent professionals. Moreover, no case law appears to exist at the present time in which the new approach with respect to obviousness used by CIPO has been reviewed by a court. However, it is clear that they have the potential to create significant problem should Examiners apply the guidance of the practice notice *verbatim*. For example:

(1) The practice notice sets out that "the subjective experience of the inventor will not be considered relevant unless it can be established that it reflects that expected from the hypothetical skill in the art". Although the wording of the final practice notice was changed to a more open one than that of the earlier version, CIPO appears to remain reluctant to consider the course of conduct of the inventor. However, in order to apply the law as set out in Sanofi, CIPO must be ready to consider the course of conduct of the inventor, as the Supreme Court did. Failure to do so could result in the CIPO's findings with respect to obviousness being different than those of the courts.

Time will tell if, as was rightly pointed out in both FICPI's and IPIC's comments, evidence such as inventor's CV and affidavits, which are routinely submitted to CIPO, can be used successfully to assess if the inventor is a skilled person, and to review the course of conduct.

- (2) The practice notice sets out guidance that departs from the law, for example by substituting its own language for that of the law as set out in *Sanofi*, (e.g., see points 2-3 and 5). This is confusing at best for Examiners, and it is not clear at the present time if this lack of consistence between CIPO and the court will taint the obviousness analysis.
- (3) The practice notice does not encourage Examiners to formally document (e.g., by citing appropriate references) information that they believe is common general knowledge, explicitly stating that "they need not identify" documents establishing the common general knowledge. It was proposed that this is likely to be unworkable and unduly prolong examination. Examiner should be encouraged to cite an appropriate prior art reference establishing what constitutes common general knowledge and avoid baseless allegations of common general knowledge.
- (4) The use of the language pertaining to "problem and solution" appears to be an attempt at introducing into Canadian practice a method of assessing obviousness used in Europe. Kindly refer to our answers to Questions 14 and 15 in this regard.

Regional and National Patent Granting Authorities

32. If you have two patent granting authorities covering your jurisdiction, do they diverge in their approach to inventive step / non-obviousness?

N/A

33. If yes, is this problematic?

N/A

II. PROPOSALS FOR HARMONIZATION

The Groups are invited to put forward proposals for the adoption of harmonised rules in relation to the patentability criteria for inventive step / non-obviousness. More specifically, the Groups are invited to answer the following questions without regard to their national laws:

34. Is harmonization of inventive step / non-obviousness desirable?

Yes.

35. Is it possible to find a standard for inventive step / non-obviousness that would be universally acceptable?

Probably not.

- 36. Please propose a definition for inventive step / non-obviousness that you would consider to be broadly acceptable.
- 37. Please propose an approach to the application of this definition that could be used by examiners and by courts in determining inventive step / non-obviousness.

Summary

Non-obviousness was only included as an express provision in the Canadian Patent Act in 1996. However, obviousness has always been a bar to patentability in Canada.

The problem/solution approach for assessing non-obviousness, while possibly persuasive, is not determinative under Canadian law. In Canada, the inventive concept of a claim under examination is identified without regard to the prior art. Identifying the problem being addressed by the solution of the claim is done in the context provided by the description, and not by reference to the closest prior art.

Whether advantageous effects must be disclosed in the as-filed specification for other subject matter has not been settled under Canadian law. While an applicant may attempt to rely upon undisclosed advantageous effects in order to overcome cited art during prosecution, such an approach may not survive judicial scrutiny during litigation.

Finally, although "Teaching away" is not codified into any Canadian statute, it is an important consideration in establishing the state of the art and motivations of a skilled person during an obviousness inquiry, both during prosecution and before Canadian courts.

Résumé

- La non-évidence n'a été incluse que comme disposition explicite dans la Loi canadienne sur les brevets de 1996. Cependant, au Canada, l'évidence a toujours été considérée comme un obstacle à la brevetabilité.
- L'approche problème/solution visant à évaluer la non-évidence, même si elle peut être convaincante, n'est, selon la loi canadienne, pas déterminative. Au Canada, le concept d'invention d'une réclamation sous évaluation est identifié sans égards à l'artifice précédent. L'identification du problème qui est solutionné par la revendication est effectuée selon le contexte fourni par la description, et non pas en référence à la technique antérieure la plus proche.
- Le fait que les effets avantageux doivent être divulgués ou non dans la spécification telle que déposée pour d'autres matières n'a pas encore été défini par la loi canadienne. Alors qu'un requérant peut tenter de se reposer sur les avantages non divulgués afin de contourner la technique antérieure citée pendant le procès, une telle approche ne résisterait pas à l'examen juridique pendant le procès.
- Finalement, même si le "Teaching away" (décalage avec le sujet revendiqué) n'est codifié dans aucune des lois canadiennes, il représente une considération importante dans le processus d'établissement de l'état de la technique et la motivation d'un spécialiste pendant une enquête d'évidence, autant pendant le procès que devant les tribunaux canadiens.

Zusammenfassung

- Nichtoffensichtlichkeit wurde lediglich als eine ausdrückliche Bestimmung im kanadischen Patentgesetz von 1996 einbezogen. Offensichtlichkeit war jedoch schon immer ein Ausschlussgrund der Patentierbarkeit in Kanada.
- Der Problem-/Lösungsansatz zur Bewertung der Nichtoffensichtlichkeit ist nach kanadischem Recht nicht ausschlaggebend, obwohl er möglicherweise überzeugend ist. In Kanada wird das erfinderische Konzept eines zu untersuchenden Anspruchs identifiziert, ohne dass der Stand der Technik betrachtet wird. Die Identifikation des Problems, das durch die Lösung des Anspruchs angesprochen wird, wird im durch die Beschreibung bereitgestellten Kontext vorgenommen und nicht durch Bezugnahme auf den nächstliegenden Stand der Technik.
- Nach kanadischem Recht ist noch nicht geklärt, ob die vorteilhaften Wirkungen in der wie in der Anmeldung eingereichten Beschreibung für sonstige Gegenstände offengelegt werden müssen. Obwohl ein Anmelder es versuchen mag, sich auf nicht offenbarte vorteilhafte Wirkungen zu verlassen, um den zitierten Stand der Technik während der Rechtsverfolgung zu umgehen, übersteht eine derartige Vorgehensweise die gerichtliche Prüfung während des Prozesses möglicherweise nicht.
- Obwohl "von der Lehre wegführen" (der Stand der Technik führt von der Erfindung weg) in keinem kanadischen Gesetz kodifiziert ist, ist dies letztlich eine wichtige Erwägung bei der Ermittlung des Standes der Technik und den Motivationen eines Fachmanns während einer Prüfung der Offensichtlichkeit, sowohl während der Rechtsverfolgung als auch vor den kanadischen Gerichten.